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The effect of different inflated air insole in the foot plantar pressure

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Abstract

Background: *Exercise promotes health in people with diabetes. Weight-bearing activities increase the risk of foot ulcers. Air-pressure shoes may relieve high plantar pressure.*
Objective: *Nevertheless, no study has investigated whether air-pressure shoes affect the plantar foot.*
Methods: *A repeated measures study design, with five healthy subjects tested with three inner air pressures (80, 160, and 240 mmHg) and 20 minutes of walking to examine their effects on peak plantar pressure (PPP). PPP after walking was measured from the forefoot in the big toe (T1), first metatarsal head (M1), and second metatarsal head (M2). We used a one-way ANOVA to analyze the results.*
Result: *We found that after walking for 20 min, inner air pressure significantly affected plantar pressure in the M1 and M2 (P = 0.008 and 0.006, respectively). Regarding the inner air pressure effect, there was a significant difference in the M1 head between 80 and 240 mmHg (274.2 ± 35.6 kPa vs. 689.4 ± 106.3 kPa, P = 0.002) at 20 minutes of walking duration. Moreover, there was a significant difference in the M2 head between 80 mmHg and 240 mmHg (250.6 ± 30.1 kPa vs. 572.4 ± 87.3 kPa, P = 0.002) and 160 and 240 mmHg (396.6 ± 35.3.7 kPa vs. 572.4 ± 87.3 kPa, P = 0.050). This finding is significant*

because the higher inner air pressure shoes can increase plantar pressure compared to 80 mmHg inner air pressure.
Conclusion: *Based on the findings of this study, it is recommended that individuals at high risk of developing foot ulcers wear shoes with inner air insoles (80 mmHg).*

Keywords*: air insole; foot ulcer; mechanical properties; metatarsal head; walking*

INTRODUCTION

It has been demonstrated that physical activity benefits health and reduces the risk of chronic complications in individuals with diabetes mellitus (DM) as well as peripheral vascular disease (Liao et al., 2019). According to the American Diabetes Association (ADA), DM people should engage in vigorous aerobic exercise for 75 minutes each week or moderate-intensity aerobic exercise for 150 minutes each week (ADA, 2020). A study has demonstrated that moderate and vigorous levels of exercise are effective in improving peripheral circulation, but light levels of exercise do not (Liao et al., 2019; Mak, Zhang, & Tam, 2010; Weist, Eils, & Rosenbaum, 2004). Both people with and without diabetes usually engage in walking as a common exercise (Wu et al., 2021; Wu et al., 2020).
The risk of DFUs among DM people is greatly increased by walking because increased peak plantar pressure (PPP) increases the incidence of DFUs (Haris, Firman, Irawati, & Rahman, 2022; Lung et al., 2021; Wu et al., 2020). Wearing proper insole material for stiffness optimization can reduce the PPP. Plantar tissue injuries and stress fractures of the metatarsals may be more likely to occur when wearing a stiffer insole (Haris et al., 2021; Wu et al., 2020). In addition, several studies have demonstrated that continued physical stress over the skin significantly contributes to the development of plantar tissue injury (Haris et al., 2021; Lung et al., 2021).

Furthermore, several studies have demonstrated that proper insoles stiffness would reduce the PPP as well as decrease the risk of developing DFUs (Speed, Harris, & Keegel, 2018; van Netten et al., 2018; Zulkifli & Loh, 2020). Kim et al. analyzed the effects of air insole associated with the use of space fabric on the dynamic balance abilities of young adults (G.-C. Kim, Lee, Kim, & Nam, 2015). It has been demonstrated that the air insole reduces sway and promotes balance when subjects wear air-insole shoes. Chang et al. prototyped a multi-airbag adaptive insole (Chang & Lee, 2003). Additionally, the method can be used to design and manufacture athletic and personal insoles and medical therapeutic insoles. However, researchers did not propose a statistical analysis of its use for gaining different PPPs.

Moreover, to prove the strength of the intended sensing pad, Kim et al. examined nine inflated air insoles to achieve accuracy and precision (K. Kim, Shin, & Kong, 2018). The results indicate that different inflated air insoles have some kilogram-force accuracy errors. Still, the study did not discuss differential plantar pressure between inflated air insoles. However, no study has evaluated the effects of various inner air pressure on the mechanical properties of the plantar foot in healthy people.

This research is the first study to compare inner air pressure shoes and plantar pressure patterns after 20 min walking durations. Based on the findings of this research with healthy subjects, an understanding of the effects of walking can be provided. Therefore, this study aims to explore the effects of various inner air pressure and walking duration on healthy plantar pressure subjects. We hypothesized that different inner air pressure insole shoes (80, 160, and 240 mmHg) cause different plantar pressure patterns.

METHOD

Research Design

A repeated measures study design, including three inner air pressure (80 mmHg, 160 mmHg, and 240 mmHg) and 20 min walking duration, was used in this study. There were three different walking procedures tested in this study. During the first week of the study, the participant received a procedure of 80 mmHg, then 160 mmHg in the second week, and then the final protocol of 240 mmHg in the third week. The walking speed setting is moderate to fast (3.6 mph). Each procedure was divided by 7 ± 2 days. Three walking procedures, namely: 1st walking procedure: wearing shoes (air pressure: 80 mmHg) for 20 min; 2nd walking procedure: wearing shoes (air pressure: 160 mmHg) for 20 min; 3rd walking procedure: wearing shoes (air pressure: 240 mmHg) for 20 min.

Subjects

This study recruited healthy participants with shoe sizes 41-43 (males) and 37-39 (females) from Asia University, Taichung, Taiwan, aged 18 to 40. Their BMI was no more than 23 kg/m^2 (Pan & Yeh, 2008). Applicants were excluded if they had DM, active foot ulcers, hypertension, vascular diseases, or could not walk for 20 minutes independently or at a speed of 3.6 mph. Participants signed an informed consent form approved by the Institutional Review Board of China Medical University (No: 111-017) before the screening and experimental procedures. The examinations were conducted to maintain a comfortable environment. Furthermore, the temperature was set at 24 ± 2 °C to maintain a comfortable temperature in the room.

Experimental Procedures

In order to prevent the effects of prior weight-bearing activity on the mechanical plantar tissue property, the participant removed their socks and shoes prior to taking part in the walking protocol. The participant lay in a supine position for 30 minutes before beginning the walking protocol. Participants were instructed to walk continuously on a treadmill at a constant pace (3.6 mph) (Haris et al., 2021; Lung et al., 2021; Wu et al., 2020) on the first visit with an appropriate size of standard shoes (Hsin He Hsin Co., Ltd., Taichung, Taiwan) at an inner air insole with 80 mmHg pressure. The inflated air insole was made by using thermoplastic polyurethane material properties. A prior study showed that thermoplastic polyurethane (TPU) was a good insole material for pressure reduction (Haris et al., 2021). Measurement of plantar pressures was conducted using the plantar pressure insole measurement system (Tekscan, South Boston, MA, USA). It is necessary for the participant to wear the insole sensors inside the shoe for three minutes before the calibration. Insole sensors were calibrated in accordance with manufacturer's instructions (Jan, Lung, Cuaderes, Rong, & Boyce, 2013; Lung, Hsiao-Wecksler, Bums, Lin, & Jan, 2016). Data on plantar pressure were collected at a frequency of 300 Hz. Following the 20-minute walking session, participants returned to the laboratory to perform 160 mmHg on their second and 240 mmHg on their third visit. We evaluated three regions of interest (ROI) in the big toe (T1), first metatarsal (M1), and second metatarsal (M2) after they finished walking for 20 minutes.

(see figure 1)

Statistical Analysis

Using a one-way analysis of variance (ANOVA), we compared the PPP between three inner air pressures (80, 160, and 240 mmHg) in 20 min walking durations. The PPP measurement focused on the forefoot, especially in the big toe (T1), first metatarsal (M1) head, and second metatarsal (M2) head. A MATLAB R2020b program (Mathworks, Inc., Natick, MA, USA) was used to analyze Fscan data.

(see figure 2)

RESULT

Five non-DM, healthy participants (two men and three women) were enrolled in this study. According to the demographic data (mean ± standard deviation): age, 25.2 ± 6.2 years; height, 169.2 ± 6.5 cm; weight, 59.4 ± 7.4 kg; and BMI, 20.8 ± 2.4 kg/m^2. The one-way ANOVA showed that the inner air pressure had a significant main effect on the first metatarsal head (M1) and second metatarsal head (M2) ($P < 0.05$) but not on the big toe (T1) (Table 1). Under 20 minutes of walking duration, there was a significant difference in M1 plantar pressure between 80 mmHg and 240 mmHg (274.2 ± 35.6 kPa vs. 689.4 ± 106.3 kPa, $P = 0.002$). In the M2, there was a significant difference between 80 mmHg and 240 mmHg (250.6 ± 30.1 kPa vs. 572.4 ± 87.3 kPa, $P = 0.002$) and between 160 mmHg and 240 mmHg (396.6 ± 35.3.7 kPa vs. 572.4 ± 87.3 kPa, $P = 0.050$).

(see figure 3)

There was a significant difference in the M1 plantar pressure between 80 mmHg and 240 mmHg (274.2 ± 35.6 kPa vs. 689.4 ± 106.3 kPa, $P = 0.002$). In the M2, there was a significant difference between 80 mmHg and 240 mmHg (250.6 ± 30.1 kPa vs. 572.4 ± 87.3 kPa, $P = 0.002$) and between 160 mmHg and 240 mmHg (396.6 ± 35.3.7 kPa vs. 572.4 ± 87.3 kPa, $P = 0.050$). The data were presented as mean ±

standard errors; *, a significant difference ($P < 0.05$); **, a significant difference ($P < 0.01$).

(see table 1)

DISCUSSION

This study investigated different inner air pressure insole on PPP response in non-DM. By inserting the TPU insole under the foot, we were able to achieve a 'customized' inflated air insole that enhanced the redistribution of pressures. The use of these treatments should result in similar function rates for non-DM feet if the lower PPP is the key to reducing the risk of forefoot ulcers. Prior study has determined the TPU as the "gold standard" of care for PPP reduction, ranging from 30-40%. According to the results of this study, the inner air pressure insole (80, 160, and 240 mmHg) is a significant factor in inducing plantar pressure after the 20 min walking duration.

The findings showed that after 20 min walking, the PPP on 80 mmHg inner pressure was significantly lower in the M1 region as well as in the second metatarsal (M2) region. Still, the T1 difference was insignificant. Based on the inner air pressure effect, after 20 min walking duration, there was a significant difference in the M1 peak plantar pressure (PPP) between 80 mmHg and 240 mmHg (274.2 ± 35.6 kPa vs. 689.4 ± 106.3 kPa, P = 0.002) (Table 1). The 80-mmHg air insole reached the lowest PPP, possibly because the 80mmHg air insole seemed like a total contact mechanical insole. In this condition, the subjects might meet their suitable walking pattern. Additionally, the lowest PPP shown by the 80-mmHg air insole might cause a neutral subtalar joint position, neither a pronated nor supinated plantar position. The condition might affect 160 and 240 mmHg that inner air pressure pushed the forefoot region more pronated, inducing PPP on T1, M1, and M2 regions.

Moreover, elevated plantar pressures may lead to abnormal accumulations of tension over the plantar soft tissues (Liau et al., 2019). During walking, an ankle joint inflated to high levels may display high pronation (Escamilla-Martínez, Martínez-Nova, Gómez-Martín, Sánchez-Rodríguez, & Fernández-Seguín, 2013). The transformation into a pronated position might be due to accumulating tension by the inner air insole that might cause increased pressure under the forefoot on 160 and 240 mmHg. After 20 min walking, the second M2, there was a significant difference between 80 mmHg and 240 mmHg (250.6 ± 30.1 kPa vs. 572.4 ± 87.3 kPa, P = 0.002) and between 160 mmHg and 240 mmHg (396.6 ± 35.3.7 kPa vs. 572.4 ± 87.3 kPa, P = 0.050) (Table 1). During the push-off phase of walking, the TPU air insole, which provides high resilience, can effectively re-use mechanical energy at the forefoot (Ahmed, Barwick, Butterworth, & Nancarrow, 2020; Jirapongpathai et al., 2022). Polyethylene foam typically has a rebound resilience of 30% to 40% (Wang, Gong, & Zheng, 2016). Moreover, the TPU air insole material has extra resilience as a result of its cushioning function. Kwon et al. stated that when the insole's resilience of the insole more than 40% was softer than 17%, that was stiffer (Kwon, Lim, Choi, Kwon, & Ha, 2021). Furthermore, to redistribute plantar pressure and to increase contact time between the foot and the insole, the Australian Diabetic Association recommends that people with diabetes wear soft, but sufficiently resilient insoles (van Netten et al., 2018). It indicated that air insole materials might be excellent in reducing the PPP as mechanical energy properties on walking.

CONCLUSION

Insole materials that reduce PPP in various air pressures are essential for a better understanding of the effects of PPP reduction in people with DM. We established that the appropriate inner air pressure was no more than 240 mmHg. The 80-mmHg inner air pressure was the appropriate air insole, with the lowest PPP in the M1 and M2 but not in the big toe. To minimize the risk of DFUs and nurses, as healthcare member who spends the most time with patients, we recommend that DM patients wear appropriate air insole materials at appropriate walking speeds.

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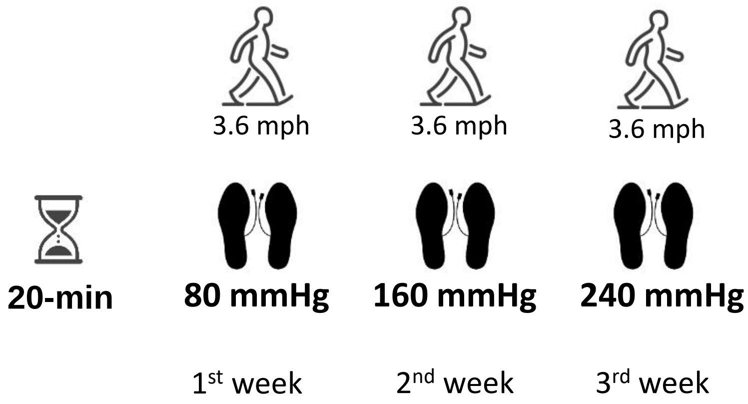

Figure 1. Walking test procedures

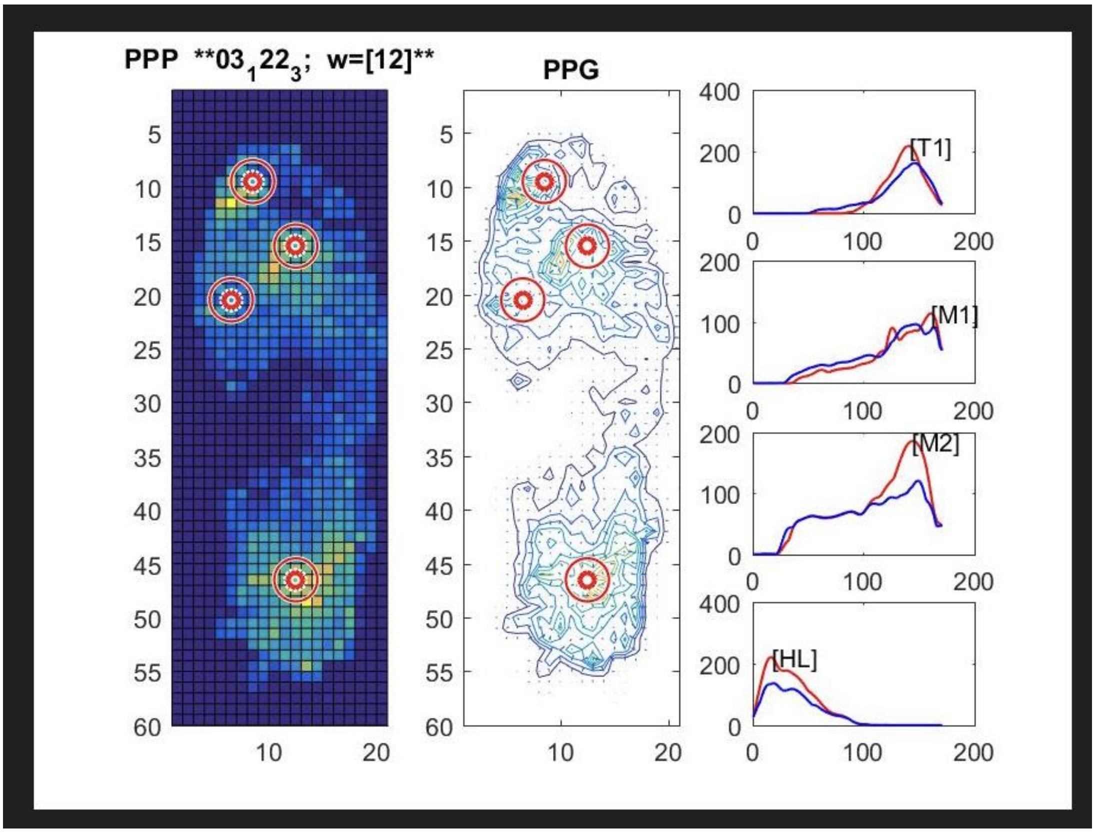

Figure 2. The plantar pressure in three regions of interest (ROI): big toe (T1), first metatarsal (M1) and second metatarsal (M2)

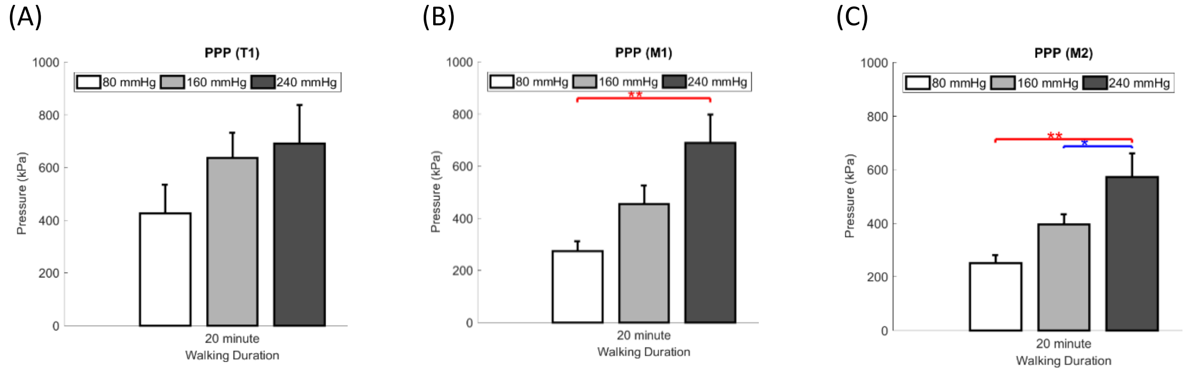

Figure 3. Comparisons of the effect of inner air pressure (80, 160, and 240 mmHg) on the plantar pressure of the big toe (T1) (A), first metatarsal head (M1) (B), and second metatarsal head (M2) (C) at 20 min walking durations

Table 1. Effect of inner air pressure on plantar pressure

Region	Duration	Inner air pressure			One-way ANOVA		Fisher LSD Post hoc				
		80 mmHg (Mean ± SE)	160 mmHg (Mean ± SE)	240 mmHg (Mean ± SE)	P value		80 mmHg vs. 160 mmHg	80 mmHg vs. 240 mmHg		160 mmHg vs. 240 mmHg	
T1	20 min	426.6 ± 107.8	635.8 ± 94.2	691.2 ± 145.4	0.283		0.233	0.138		0.745	
M1	20 min	274.2 ± 35.6	454.8 ± 70.2	689.4 ± 106.3	0.008	**	0.120	0.002	**	0.051	
M2	20 min	250.6 ± 30.1	396.6 ± 35.3	572.4 ± 87.3	0.006	**	0.096	0.002	**	0.050	*

Note: The plantar pressure under the first metatarsal head consisting of three regions, including the big toe (T1), first metatarsal (M1), and second metatarsal (M2) head; *, P < 0.05; **, P < 0.01.